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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,875	02/08/2000	Richard Griffey	IBIS-0261	1850

7590                  05/07/2002

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[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1627

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b> <i>file copy</i>	Application No.	Applicant(s)	
	09/499,875	GRIFFEY ET AL.	
	Examiner	Art Unit	
	Tomas Friend	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 22 January 2002.

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-120 is/are pending in the application.

  4a) Of the above claim(s) 1-29 and 47-120 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 30-46 is/are rejected.

7) Claim(s) 37 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 22 January 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
  1. Certified copies of the priority documents have been received.  
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

## **Detailed Action**

### **Change of Examiner's Name**

The name of the examiner of this application has changed from Thomas Prasthofer Tomas Friend.

### **Status of the Application**

Receipt is acknowledged of a response to an office action with amendment on 22 January 2002 (Paper No. 12).

### **Status of the Claims**

Claims 1-120 are pending in the present application. Claims 1-29 and 47-120 were withdrawn from further consideration by the examiner in Paper No. 10.

Claims 30-46 are being examined on their merits.

### **Corrected Drawings**

Receipt is acknowledged of 9 sheets of corrected drawings on 22 January 2002 (Paper No. 11). The drawings are accepted by the examiner.

### **Restriction Requirement**

Applicants request reconsideration of the restriction requirement imposed in the office action dated April 10, 2001. The examiner notes that the restriction requirement was made final in the office action mailed September 25, 2001 and included responses to applicants' arguments. Accordingly, the restriction requirement is not reconsidered.

### **Withdrawn Rejections/Objections**

1. The objection to claim 30 over a typographical error is withdrawn.
2. The rejections of claims 30, 34, 40, and 45 under 35 U.S.C. 112, second paragraph, are withdrawn in response to applicants' amendment and arguments.
3. The rejections of claims 30-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. J. Am. Chem. Soc. (1995) 117:8859-8860, Lim et al. J. Mass Spectrometry (1995) 30:708-714, and Loo, J.A. Mass Spectrometry Reviews (1997) 16:1-23 are withdrawn in response to applicants' arguments.

### **Maintained Rejections/Objections**

The statutory bases for each of the following rejections may be found in a prior office action.

4. The objection to claim 37 over a typographical error ("completes" vs. "complexes") is maintained from Paper No. 10. Applicants have not amended claim 37 as indicated on page 3 of Paper No. 12.

### **Maintained Rejections – 35 U.S.C. 112, first paragraph**

5. Claims 30-46 remain rejected under 35 U.S.C. 112, first paragraph, for reasons made of record in Paper No. 10.

Applicants argue that the office action "*erroneously assumes that both standard and test compounds are required to bind to the same site in the target molecule,*" and concludes that, because such an assumption was made, the enablement rejection is "*baseless.*"

Applicants' argument has been carefully considered and found not to be persuasive. The presently claimed method uses a "*standard compound*" and test compound that bind to a target molecule. The method encompasses test and standard molecules that bind to the same sites,

overlapping sites, and/or different sites on a target molecule. The presently claimed method does not exclude any category of test or standard molecules. Consequently, competitive and non-competitive binders with the same affinity would give different results compared to the same standard molecule.

Applicants argue that one skilled in the art would only need to know “*1) whether or not the standard compound binds to the target, and often 2) the approximate affinity with which the standard binds. The specification, for example, on page 34, line 1 to page 35, line 22, clearly sets forth suitable examples of standards and targets and provides ample guidance for selection of standards according to the invention.*”

Applicants' argument has been carefully considered and found not to be persuasive. Applicants assert that “*one skilled in the art would find it sufficient to know 1) whether or not the standard compound binds to the target, and often 2) the approximate affinity with which the standard binds.*” As an example, let us consider a mixture of compounds to be tested that is introduced into a test mixture according to the presently claimed invention. According to applicants' assertion, one of ordinary skill in the art would only need to know if the standard binds to the target and (often) the approximate affinity of the standard for the target. Some or all of the unknown test compounds are present at concentrations 100 times higher than that of the standard. The results of the method show that some of these compounds bind better than the standard. In this instance, the higher concentrations of test molecules would cause molecules of lower affinity for the target than the standard to be selected. Consequently, one of ordinary skill in the art would have to know something about the concentrations of the test compounds. With respect to the guidance provided in the specification on pages 34 and 35, the range of  $10^{-9}$  M to  $10^{-4}$  M for the dissociation constant between target and standard compound with a preferred range of 10-50 mM does not provide adequate guidance to one of ordinary skill with respect to the selection of a standard compound for a target because hundreds, if not thousands, of molecules would satisfy such a requirement for many target molecules, particularly charged molecules. The lists of standard molecules provided in the specification are general lists of compound classes as are the lists of possible targets. There is no guidance that would allow one of ordinary skill to assign a specific standard to a specific target without experimentation.

**Maintained Rejections – 35 U.S.C. 112, second paragraph**

6. Claims 33 and 35 remain rejected under 35 U.S.C. 112, second paragraph, for reasons made of record in Paper No. 10.

(C and D). Applicants argue that the term "*diverse compounds*" in claims 33 and 35 and the term "*related compounds*" in claim 34 are definite because "*any degree of diversity or relatedness is suitable for the invention, and one skilled in the art would understand this in light of the specification.*"

Applicants' argument has been carefully considered and found not to be persuasive. Although claims are to be read in light of the specification, limitations from the specification may not be read into the claims. Furthermore, if ANY degree of diversity or relatedness is suitable (i.e. identical to totally unrelated), than it is not clear how, for example, claim 33 further limits claim 30. The rejection is maintained.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claim 1-29 and 47-120, drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.  
04 May 2002

*J Venkat*  
DR. JYOTHSNA VENKAT PH.D  
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